

Remarks

Applicant has reviewed the Office Action mailed December 22, 2011.¹ Claims 1-16, 18-32, and 34-46 are pending prior to entry of this amendment. By this amendment, claims 36-37 are cancelled without prejudice or disclaimer of the subject matter therein, and new claims 47-48 are included. After entry of this amendment, claims 1-16, 18-32, 34, 35, and 38-48 will be pending in the application. Applicant respectfully submits the following remarks.

Interview Summary

Applicant's representative would like to thank Examiner Alyssa Alter for extending the courtesy of a telephonic interview on April 19, 2012, to discuss this case. The following recordation of the substance of the interview is believed to be complete and proper, in accordance with MPEP 713.04. It is requested the Examiner notify the undersigned if the Examiner believes this statement contains any inaccuracies or if the Examiner believes this statement is otherwise not complete and proper.

Interview Participants: (1) Examiner Alyssa Alter; and (2) Applicant's attorney, Michael J. Feller.

Claims 1, 12, 13, 25, and 27 were discussed during the interview. U.S. Patent No. 6,308,102 B1 issued to Sieracki et al. ("Sieracki") was also discussed. A proposed agenda of issues for discussion was prepared and faxed to Examiner Alter, and is included as an attachment at the end of this paper.

Applicant's representative contacted Examiner Alter with the goal of clarifying the grounds of rejection in the recent Office Action. During the interview, Examiner Alter explained that paragraph five on page three of the Office Action explained the rejection of claims 1, 12, 13, 25. In particular the Examiner explained her view that paragraph five addresses limitations related to safe/not safe and automation that are provided in claims 1 and 25. In addition, the Examiner explained that in her view the rejection of claims 12 and 13 was supported because in her view Sieracki inherently disclosed a stimulation parameter that was a set of electrodes. Examiner Alter also noted that claim 27 was rejected on grounds similar to the grounds of rejection for claim 6, which appear in paragraph 9 on page 4 of the Office Action. Applicant's

¹ Referred to further herein as the "Office Action."

representative thanks the Examiner for her clarifications, which have facilitated preparation of this response.

During the interview, Examiner Alter and the undersigned also discussed the limitations “manual mode” and “run mode” from claim 1. In particular, Applicant’s representative noted that the discussion in paragraph five of the Office Action did not seem to address these limitations. The Examiner explained that in her view Sieracki’s reference to verifying that entered data fall within consistency boundaries discloses a manual mode and that Sieracki’s reference to a “system of the present invention provides for full automation of operation” discloses the claimed run mode comprising automatically initiating the first treatment therapy, among other limitations. The undersigned respectfully disagreed and outlined his belief that Sieracki’s reference to automation was not automation in the context of a run mode different than a manual mode, but was instead a reference to the automating of the process of adjusting neurostimulation settings for a patient.

During the interview, Examiner Alter and the undersigned also briefly discussed general principles relating to obviousness determinations in the context of the pending rejection of claims 10-11, 14-16, 18-19, 21, 30-32 and 43-45 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Sieracki.

No agreement was reached regarding the rejections of the claims and the Examiner invited Applicant to set forth its arguments in response to the Office Action. No other matter of any substance was discussed in this interview.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-9, 12-13, 20, 22-29, 34-42 and 46 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,308,102 B1 issued to Sieracki et al. (“Sieracki”). Applicant respectfully disagrees with the Examiner’s rejection and requests reconsideration.

For example, Applicant respectfully disagrees with the Examiner’s rationale presented in paragraphs 4 and 5 on page 3 of the Office Action with respect to independent claims 1, 25, and 40.² Independent claim 1 provides a method comprising, among other things, operating a

² While initially unclear to Applicant, Applicant understands from the interview with Examiner Alter that paragraph 5 details the rejections of claims 1, 25, and 40, among other claims.

medical device system in a manual mode and operating the medical device system in a run mode. Claim 1 also provides that the medical device system is configured for treatment of a nervous system disorder producing one or more neurological events, and that operating in the run mode comprises automatically initiating the first treatment therapy to the patient with the medical device system in response to a neurological event if the first treatment therapy is safe.

In the Office Action, the Examiner stated that “Sieracki et al. discloses a patient interactive neurostimulation system that enables patient to operate the medical device in a manual mode.”³ The Office Action continues by citing Sieracki at col. 4, lines 31-42, which is reproduced below:

It is an essential and novel feature of the present invention that means are provided in the system which pre-sets consistency boundaries for data entered by the patient and which verify that the entered data fall within the consistency boundaries. If the consistency boundaries are exceeded, then
35 the data entered are recycled, and the patient is asked to repeat a response, or the system is checked for hardware failure. This arrangement in the system of the present invention provides for full automation of operation, obtaining of reliable data, and safety for the patient, so that he/she
40 may be confidently left alone to work with the system without intervention by a clinician.

Based on this section of Sieracki, the Office Action concludes that

Therefore when the first set of information received from a user is determined to exceed the pre-set boundaries, it is considered “not safe” and a corrective action (“recycling” or discarding the data) is executed. If the boundaries are not exceeded then the device continues with the treatment regimen.⁴

From the discussion during the interview, Applicant understands that the Examiner’s position is that Sieracki’s reference to “full automation of operation, obtaining of reliable data, and safety for the patient...” discloses the claimed run mode comprising automatically initiating the first treatment therapy as provided in claim 1. Applicant respectfully disagrees and submits that meaningful differences exist between the claimed method in claim 1 and Sieracki. For example, Applicant respectfully disagrees that the “full automation” referenced in Sieracki is the

³ Office Action, p. 3, lines 2-4.

⁴ Office Action, p. 3, lines 14-18.

same as the “run mode comprising automatically initiating the first treatment therapy ... in response to a neurological event” provided in claim 1. In one example, Sieracki notes that the patient interactive system 24 in FIG. 3 provides a computer controlled system for automatic adjustment of neurostimulation implants used in pain therapy and in treating neurological dysfunctions.⁵ Sieracki goes on to indicate that one system is “operated directly by the patient and substantially replaces the physician in the routine and tedious task of adjusting stimulation settings.”⁶ Applicant respectfully submits that the automatic adjustment of neurostimulation implants and/or adjusting stimulation settings discussed in Sieracki is not the same as “automatically initiating the first treatment therapy ... in response to a neurological event” provided in claim 1. Nor would it have been obvious to one skilled in the art to modify Sieracki to provide the run mode in claim 1 comprising automatically initiating the first treatment therapy to the patient with the medical device system in response to a neurological event.

Accordingly, Applicant respectfully submits that claim 1 is patentable for at least the reasons described above. Independent claims 25 and 40 include limitations similar to those in claim 1, and thus are believed to be patentable for at least the same reasons. Claims 36-37 are cancelled, thus rendering their rejection moot. Claims 2-9, 12-13, 20, 22-24, 34-35, and new claim 47 depend (directly or indirectly) from claim 1; claims 26-29, 38, 39, and new claim 48 depend (directly or indirectly) from claim 25; and claims 41, 42, and 46 depend from claim 40, and thus all are believed to be patentable for at least the reasons provided above.

Claim Rejections Under 35 U.S.C. § 103

Claims 10-11, 14-16, 18-19, 21, 30-32 and 43-45 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Sieracki. Applicant notes that these claims depend directly or indirectly from one of independent claims 1, 25, and 40, and thus are believed to be patentable for at least the reasons presented above with respect to the independent claims. Accordingly, Applicant respectfully requests the rejection of claims 10-11, 14-16, 18-19, 21, 30-32 and 43-45 be withdrawn.

⁵ Col. 8, lines 16-19.

⁶ Col. 5, lines 44-46.

Conclusion

Applicants submit that this application is in condition for allowance for at least the reasons presented above. Favorable consideration and prompt allowance of the application are respectfully requested. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

/Michael J. Feller/

Dated: April 23, 2012

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Ivan Osorio
Application No.: 10/687,135 Group Art Unit: 3762
Filed: 10/15/2003 Examiner: Alyssa Margo Alter
Title: Configuring and Testing Treatment Therapy Parameters for a Medical
Device System

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**PROPOSED AGENDA FOR TELEPHONIC
INTERVIEW SET FOR APRIL 19, 2012**

Applicant's representative would like to thank Examiner Alyssa Margo Alter for agreeing to discuss this case and the Office Action dated December 22, 2011. A telephonic interview has been scheduled for April 19, 2012, at 10:00 EDT. Applicant respectfully submits the following proposed agenda for discussion.

1. Rejection of claims 1, 12, 13, 25, and 27 under 35 U.S.C. § 102(e) in view of U.S. Patent No. 6,308,102 B1 issued to Sieracki et al. ("Sieracki"). The rejection of these claims and Sieracki's applicability to them was somewhat unclear to Applicant's representative. The undersigned would greatly appreciate the opportunity to clarify the grounds for rejection.
2. Rejection of independent claims 1, 25, and 40 under § 102(e) in view of Sieracki, especially related to the limitations of operating in a manual mode and a run mode.

Respectfully submitted,

Dated: April 18, 2012

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